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REMARKS

This Amendment is responsive to the Office Action dated June 9, 2011.

Claims 3, 17 and 22 have been amended. Claims 3-9, 11-17, 19-28, 30 and 38-40 remain pending in the application. Applicant respectfully requests reconsideration of the Examiner's rejections.

The claims have been amended to overcome all of the Examiner's objections.

The sole rejection pertains to the Examiner's citation of U.S. Patent No. 6,790,178 to Mault ("Mault '178") under Section 102 against Applicant's pending claims. For the reasons provided at great length below, Applicant respectfully traverses such rejection.

ARGUMENT

The purpose of a true self sufficient, self operating talking medical device is to provide audible voice assistance "at all times", without manual calibration or verbal input being required of the patient for the function of the present invention.

1. Mault does not work with or within standard traditional medical equipment. Mault's invention solely relies on a variety of personal digital assistants (PDAs) to provide the function of Mault's invention. Mault's PDA and modules are already in their own housings, for which personal digital assistants (PDAs) have many housing configurations. See Mault Col. 1, II. 35-45 for a list of Mault's PDAs. Thus, combining two separate housings such as a PDA with a traditional medical device would be impractical and impossible (i.e. Gameboy inside the housing of a traditional Spirometer). Applicant's invention always works within the housing of all medical devices of Applicant's invention, as Applicant teaches; "no other housings, other than

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the housing of the medical device itself, can be used to provide the function of Applicant's invention". See Applicant's Specification Page 16, Il. 7-8 "...the present invention and the Medical Apparatus Constructed by Constructor 10 are contained within the same Housing 14." Without a medical device, Applicant's claimed invention has no housing whatsoever. This difference, in comparison to Mault, is what the Applicant claims and teaches as the function of Applicant's invention, thus, making Mault and Applicant totally different inventions.

- 2. Mault's invention cannot and does not provide voice in connection with "any" existing traditional medical devices. Rather, Mault teaches instead, a limited method for providing a means in which ratios and parameters can be determined by using a variety of Personal Digital Assistants and monitor modules. Whereas, Applicant's invention claims only one embodiment, not a variety, as Applicant remains the same invention at all times. Applicant's invention works with each traditional standard medical device as a unit in whole, "in synthesis" within each medical device's existing structure. This function of a providing a single configuration, in comparison to Mault (i.e. variety of PDAs), is a distinct difference between Mault and Applicant's invention.
- 3. Mault's electronic assembly was never intended to be a part of, work within, or even be associated with any existing traditional medical device, as Mault never claims improving or having any direct contact with any traditional medical devices. Mault's invention makes no contact with any commercially available traditional medical devices, as obviously this is not what Mault intended to be the function of Mault's invention. Applicant is intended to work solely with available existing commercial traditional medical devices, showing an important difference between Applicant and Mault.

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- 4. Mault does not provide or teach PDA/modules that house pressurized gases (i.e. oxygen tank, artificial breathing apparatus, ventilators of different types in comparison to Applicant's device which are utilized as pressure holding tanks; Aerosol devices and pressure apparatuses which require air compressors for forced delivery; warning devices which will warn the operator as to critical parameters; anesthesiology apparatuses or machinery which require pressure held gases). Applicant's electronic assembly is in synthesis ("one with") each of these claimed devices, thus becoming one and the same medical device, for providing voice in synthesis with the medical device itself. Mault's PDAs and physiological monitor modules are incapable of performing pressurized functions, as Mault's PDA/modules do not hold pressure. Mault's invention is limited in many distinct ways in comparison to Applicant.
- Applicant's device is a unitary device and the electronic components of Applicant's invention are not distributed. Applicant's is a common housed device.
- 6. Mault's PDA need not be a unitary device. "PDA need not be a unitary device, but instead the components could be distributed." Col 4., Il. 30-21. Obviously, Mault is not a common housed device.
- 7. Applicant's invention works with dedicated devices and is a non-programmable device. Mault's invention does not. This is especially important as Mault teaches "dedicated and non-programmable devices" are excluded for the function of Mault's invention. Col 4, Il. 39-40.
- 8. Mault's device requires assistance, as well as, the user must provide verbal and manual participation. See Mault Col 6, ll. 64-65 "For example, a particular user may specify that they will walk or run a certain number of times and for a certain distance each week," Applicant does not.

as Mault did not invent PDAs.

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9. Mault relies on separate electronic assemblies using personal digital assistants and monitor modules, in which Mault teaches are not continually the same, as it is up to the user as to decide what PDA is being used. Applicant always relies on the same single electronic assembly and Applicant's user has not control of the medical devices function or what electronic assembly is being used, as applicant's invention remains the same at all times. Mault's does not,

- 10. Applicant's invention replaces outside assistance and automatically works on its own without any user information being needed to be entered (i.e. verbal or manual). Mault's does not. See Mault Col. 10, ll. 54-56 "...the user first inserts the attachment flange 62 into the accessory slot to couple the spirometer module 60 with the PDA 66."
- 11. Whereas Mault depends and relies solely on the user entering any information for the function of Mault's invention, Applicant's device requires no entering of information by the user.
- 12. Applicant's invention automatically provides verbal warnings. Page 25, 1. 11 and 1. 23 "One function of the present invention as described above in the specification is to give an immediate audible, verbal warning and reading as necessary to alert." And "...the present invention can provide an audible, verbal, response and warning, as necessary...". Mault does not teach any warning capabilities for Mault's monitor module system. Obviously, Mault's invention was not intended for this purpose, as PDAs are not new or novel and are not meant for the purpose of providing warnings of any kind.
- 13. Mault does not teach the ability for Mault's invention to turn "off" by itself. Applicant teaches that the medical device turns off and on without manual assistance. Page 7, Il. 10-13 "The functional program will at a predetermined time engage the operation of each device in order to guarantee each

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operation been performed by the patient as well as, turn off and on the medical apparatus at said predetermined times to allow proper fulfillment of said therapy in which verbal guidance is being employed.

- 14. Mault claims and teaches "other" means, besides voice, for patient interaction are acceptable for the function of Mault's invention. Col. 24, ll. 64-66 "However the user may interact with the PDA ...using any suitable method is acceptable". Voice generation is not new or novel to known PDAs. Applicant's talking medical device is solely dedicated to voice for all of the functions of Applicant's invention for all patient interaction.
- 15. When Mault requires voice generation by the user to provide the function of voice for Mault's PDA/module system, Mault limits the PDA/module system to only being able to provide voice when the patient can talk or speak. If Mault's patient cannot talk, then Mault's PDA/monitor module cannot provide any voice.
- 16. Mault PDA/module system "does not" automatically work on its own without participation of user calibration or user verbal input assistance. Applicant's invention always works totally on its own as Applicant's invention is preprogrammed to work without patient verbal input or calibration assistance.
- 17. Mault requires setup tasks to be performed by the patient for function of Mault's PDA/monitor system in all scenarios (i.e. user voice recording, generation and recognition, user attachment of flange to PDA, and other user calibration etc.). Applicant requires "no additional" tasks by the patient for function of Applicant's invention. Mault's PDA voice is not new or novel.
- 18. Mault has limitations relating to Mault's possible ability for voice as the PDA cannot always provide voice (i.e. only "If" the PDA has voice capabilities, voice can be provided for Mault's PDA/module system. Col 5, Il. 5-6 "If the

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PDA and module combination includes voice generation capability..."). Please note: many PDAs do not provide voice capabilities and Mault did not invent PDA or PDA voice.

19. Mault's invention heavily relies on non-verbal displays as Mault teaches "any suitable means for patient interaction is acceptable" Col 24, Il. 62-67. Thus, with this understanding, the patient who is blind is prevented from using Mault's device. Applicant's invention always provides voice for all medical instructions and measurements, improving the medical device in all scenarios. Applicant's invention simultaneously provides displays, along with voice accordingly, to provide use of the Applicant's invention for the blind.

THE EXAMINER STATES:

The Examiner emphasizes the position that: "further discussions of the PDA's capabilities are equivalent to a stand-alone module's capabilities." Page 4 of June 9, 2011 OAS. Using the Examiner's stated position, it is obvious that there is no way for the spirometer/calorimeter module to generate any power source in order to produce sound amplification to provide voice, as Mault teaches neither modules have their own controls or onboard CPU. Mault col.7. Il. 44-47 "...the calorimeter module for use with the present invention preferably does not include its own controls, display, or onboard CPU." and Col 10, Il. 43-44 Therefore, a simplified calorimeter may be used a spirometer...". Thus, without electronics neither the calorimeter or spirometer modules are stand alone devices as taught by Mault. These principles and requirements for operation of Mault's module evidences the functions of both the spirometer and calorimeter modules as being the same and, thus, showing a significant difference between Applicant and Mault. Applicant's invention is always a stand alone at all times and voice is always used in every medical scenario in all of Applicant's devices, as the power and controls are always within the embodiment of Applicant's invention. In all scenarios Applicant's invention is truly a stand-alone device. Applicant's devices are non-programmable and dedicated

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in which the electronic assembly is within each of Applicant's medical devices. Mault's invention excludes dedicated and non-programmable devices, thus, showing an unarguable difference between Mault and Applicant. See Mault Col. 4, Il. 39-40 "Mault's preferred embodiment excludes "dedicated devices" and non-programmable devices."

Utilizing the Examiner's position that: "further discussions of the PDA's capabilities are equivalent to a stand-alone module's capabilities" (Page 4 of OAS). Mault could not provide any gauging or otherwise with the aforementioned understanding in which Mault's above stated calorimeter is taught "not" to have any controls, display or onboard CPU. Thus, these modules are not able to provide "speech recognition, voice generation, voice recording, wireless or wired communication or any other capabilities" (Mault Col 9, II, 31-33). Under this understanding, with due respect to the Examiner, Applicant respectfully requests that the Examiner note that Mault teaches; "Therefore, a simplified calorimeter may be used a spirometer..." Col 10, IL 43-44. With the understanding from Mault Col. 7, Il. 44-47 "The calorimeter module for use with the present invention preferably does not include its own controls, display or onboard CPU. Using the Examiner's above stated position regarding "further discussions" that the stand alone module is equivalent to a PDA, neither the calorimeter module nor the spirometer module could have gauging capabilities. Using Mault's own teachings, without an electronic assembly in specified modules, gauging would be impossible. The above teachings would also eliminate voice generation, voice recognition, voice recording and the use of a speaker for sound in the aforementioned module, since these features require an electronic assembly to be a stand-alone device. It would be obvious that a speaker could not be used without a power source for the amplification of sound. Thus, Mault's voice generation is incapable of being claimed by Mault, making Mault distinctively different than Applicant's preprogrammed voice per the aboveevidence relying on the Examiner's proclaimed position, regarding PDAs being equivalent to stand-alone modules and Mault's modules not having an electronic assembly. It would be obvious to one skilled in the art that Mault and Applicant are completely different inventions, as Applicant always requires an electronic assembly, whereas Mault does not. Thus, Mault is obviously not a self-sufficient, self-operating, valid talking medical device.

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The Examiner has stated, Page 3 of the OAS, II. 3, 17 and 22; Mault's module having computing capabilities incorporated into the module housing, such that the module becomes a gauging mechanism and stand-alone device with its own processing electronics. Also, Page 3 of OAS, the Examiner has concluded; Mault has a particular gauging mechanism of the monitor modules that provide a function of the present invention, e.g. spirometer, etc. (Mault Col. 4, 11. 41-56). On page 3 it is also noted that the Examiner is in agreement with Mault taken the position that; the physiological monitor may be operational without being interconnected or in communication with a PDA and that the monitor may have onboard data processing (Mault Col. 5, Il. 25-28). Emphasis was added by the Examiner. On page 4, the Examiner quotes that the PDA and module combination includes voice generation capability, as part of the module itself or as an additional accessory and the voice commands may be generated (Mault Col. 5, Il. 4-10). Also on Page 4 the Examiner added "with emphasis" that the monitor module may include onboard wireless communication capability and necessary sensors, memory, and communication hardware forming part of the chip. (Mault Col 6, Il. 3-14) Emphasis again being added by the Examiner. The Examiner on page 4, paragraph 4, the Examiner takes the position that: "further discussions of the PDA's capabilities are equivalent to a stand-alone module's capabilities." With this position of the module of Mault having the functionality of the PDA (i.e. common house stand-alone device, with an electronic assembly, voice generation capabilities, etc.), the Applicant respectfully makes the following the points of differences between Mault and the Applicant.

APPLICANT ANSWERS:

Though Applicant respectfully answers the Examiner's above noted interpretation and for purposes of showing important significance of these remarks regarding the Examiner's position, the Applicant will assume, arguendo, that the Examiner's interpretation is accurate. With this said, even if Mault provides a particular gauging mechanism module, i.e. spirometer, etc., it is important that the Examiner note, that Mault teaches that Mault's modules would be incapable of working with the above Examiner's position? Mault at Col 7, Il. 45-47 specifically states: "the calorimeter module 12 ... does not include its own controls, display or onboard CPU". This

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shows significant difference between Mault and Applicant, using the Examiner's position. Another important point is that Mault's modules, as described above have no capabilities for voice generation, voice recognition or voice recording using Mault's own teachings. Mault also does not have the ability to provide power for amplification of a speaker, again showing significant difference between Mault and Applicant as without the module having its own controls, displays or onboard CPU there can be no voice. Using the Examiner's stated position, Mault's and Applicant's inventions are obviously quite different. For a more detailed comprehension, the Applicant suggests that the Examiner read the following in view of the Examiner's position.

SPIROMETER MODULE

Mault's Spirometer module which uses a calorimeter, is unlike the Applicant's traditional spirometer, which uses a "float" within a bell jar to show the measurement of patient flow rates (as shown in Exhibit C herein), not the flow tube, as Mault teaches.

Mault col.10.ll;43-44 "Therefore, a simplified calorimeter <u>may be used as a spirometer</u>..." Mault col.7.ll;44-47 "...the calorimeter module for use with the present invention preferably does <u>not include its own controls, display, or onboard CPU."</u> The examiner's stated position (Page 4 of June 9, 2011 OAS) is that: "further discussions of the PDA's capabilities are equivalent to a stand-alone <u>module's capabilities.</u>" Please note that the simplified calorimeter does not have "controls, displays or onboard CPU", which means that Mault's spirometer also does not have "controls, displays or onboard CPU" in the module itself. Thus, neither can provide voice. Please keep in mind in consideration that the Applicant has shown that the two stated modules (i.e. calorimeter and spirometer) cannot work for voice and this fact should provide persuasion to the Examiner of the reason as to why Applicant and Mault are truly different inventions. When examining Mault's Calorimeter Module, one finds that the method of measuring FEV (Forced Expiration Volume) as taught by Mault, is accomplished through physiological sensors which make no contact with a mechanical gauge. Thus Mault's method of

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using "physiological" sensors (meaning Mault's sensors only work with living organisms). The sensors of Mault only work directly when in contact with the breath of the patient (i.e. part of living organism), when the patient breaths in the flange (i.e. spirometer flow tube). At that time the patient's breath or gas makes direct contact with the physiological sensors in the "flow tube of the flange". The sensor detects the living physiological parameters of the living materials of the human breath (i.e. cells, saliva, etc.), to provide ratios, parameters and determinations. Mault makes no contact with a mechanical non-living gauge of any standard medical apparatus at any time, nor or is it possible for Mault's physiological modules to communicate with any mechanical gauge. This further identifies the purpose of Mault's invention teaching only the use of physiological monitors to provide data from a living organism. It is known that physiological monitors cannot retrieve data directly from a mechanical gauge (i.e. for example; polymer floats or balls within the housing of traditional spirometry devices), which is the function of Applicant's standard medical devices. Mault's sensors do not and cannot gauge any non-living organism. Applicant's can. Please note: Traditional medical devices, for which Applicant's claimed invention is directed, are made of non-living material, used to gauge patient performance, through non-living mechanical gauges. Applicant's gauges are permanently encapsulated within the housing of the medical devices themselves. Mault's physiological sensors cannot work with standard traditional gauged medical devices, as it is commonly known, physiological modules only relate to living material, thus showing difference in function between Mault and Applicant. Obviously, Mault's physical monitors are unique in their ability to perform a healthcare function, however, they are not the same invention as Applicant.

Mault's physiological monitors must work as defined:

Physiologic Monitoring:

The continuous measurement of physiological processes, heart rate, renal output, reflexes, respiration, etc., in a patient and is the measurement of their metabolites in the blood, breath, tissues, or urine. This definition is also specifically taught by Mault col.7.ll;39-41 "In use, a patient breathes through the respiratory connector for a period of time and the module measures parameters..." Please note, Mault respiratory connector makes no direct connection

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with any mechanical gauge, unlike Applicant. In Mault, physiological parameters and metabolic rates of the living organism are detected solely in the breath using Mault's monitor module. Mault col.7.ll; 43-44 "These measurements may be used to determine metabolic rate." (Metabolic relates to humans and is physiological.) So, how does Mault's physiological sensor provide data for the device without being able to retrieve data from traditional mechanical gauges as the Applicants does? Mault 7.ll;35-39 "...the calorimeter module includes a body with a respiratory connector extending from the side. The body contains an internal flow path, a bidirectional flow meter, and one or more gas concentration sensors." With this understanding, Mault's PDA/monitor system makes direct contact with the gas, not the mechanical gauge. Mault's and Applicant invention are distinctively different.

It is understood that Mault has come up with a novel module/PDA combination. However, Mault's invention is completely different from Applicant, as Applicant works with traditional medical devices, whereas Mault uses physiological modules with sensors. Applicant uses the mechanical gauge of the medical device itself, whereas Mault's modules are not associated with any traditional medical gauge/device to determine any measurements.

For a better understanding of how gases play a role in relationship to Mault's flow tube in the ability to obtain results from the human body (i.e. breath). The idea that a gas could be generated in the body to regulate various physiological functions would have been hard to imagine, even unthinkable, until the discovery of nitric oxide's role in the body's vital functions. See "Nitric Oxide Breath Analysis: A Method For Monitoring Inflammation In Asthma" by (November Laurie Duckworth RN. et al., Jacksonville Medicine 1999) (http://www.dcmsonline.org/jax-medicine/1999journals/nov99/noba.htm), which is incorporated by reference. The article discusses monitoring exhaled nitric oxide to enhance one's ability to assess and monitor the asthmatic patient. The article also discusses the mounting evidence that nitric oxide plays a key role in the physiological function of the airways and may serve as a suitable indicator of airway inflammation.

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Please note that the gauge of a traditional spirometer is within the housing as **shown below** (the blue plastic float that moves up and down the bell jar when the patient breaths). This mechanical (i.e. non-living organism) float provides the patient levels denoting the patient's volume of respiratory performance and flow rate as it moves up and down within the bell jar below coinciding with the numbers shown below.

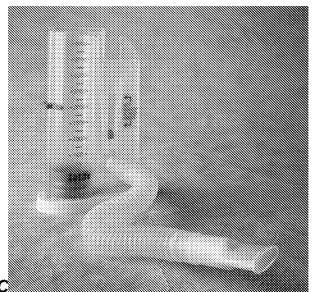


EXHIBIT C

Handheld Manual Spirometer - Adult Incentive Spirometer, Ball Type, 4000mL

In the June 9, 2011 OAS, the Examiner states that it is the Examiner's position that "all of the computing capabilities of a computing device may be incorporated in the housing of the module." (i.e. "a PDA may be incorporated into the module's housing such that the modules become a <u>stand-alone device</u> with its own processing electronics") Also, the Examiner states "During the use of the monitor module (pg. 4 OAS)...the PDA and module, combination includes voice generation capability, either as part of the PDA itself or as part of the <u>module itself.</u>").

Again, as aforementioned, Mault teaches the calorimeter module has "no" electronic assembly. It is known that an electronic assembly is required for providing "any" voice, but Mault teaches a calorimeter does not contain "its own controls, display or onboard CPU." Mault Col 7, Il. 44-47. Obviously, Mault's device is not capable of being a true voice producing medical device in all scenarios. To the contrary, Applicant's invention constitutes a true self

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sufficient, self operating talking medical device at all times providing voice within every medical device that traditionally does not include voice. Applicant's invention uses voice in all scenarios as the function of the present invention. Mault does not.

Since Mault teaches that the calorimeter is used for the same function as the Spirometer Module..See Mault col.10.ll;43-44 "Therefore, a calorimeter module may be used as a spirometer" It should be noted; that the calorimeter is normally not considered as a medical device. Defined: Measurement of the amount of heat evolved or absorbed in a chemical reaction, change of state, or formation of a solution. However, Mault teaches the calorimeter module to be used to perform the function of the spirometer. This embodiment of the spirometer (i.e. flange connector), does not work with the mechanical area of the traditional spirometer itself. Mault's physiological modules only work inside the flow tube of Mault's spiromenter, not the medical housing. The tube is referred to as the flange in Mault's teachings and is not a medical housing of any traditional medical device. It is known that PDAs are not mechanical and are not medical devices, nor is the flow tube (flange), considered a medical device in traditional medicine. Using the Examiner's position of the module having the same electronics as the PDA in Mault's teachings (Mault col.7.11;44-47 "...the calorimeter module for use with the present invention preferably does not include its own controls, display, or onboard CPU."), Mault's monitor module is obviously incapable of providing any voice data or instructions as Mault's calorimeter module has "no" electronic assembly per Mault's own teachings. Respectively, this would mean that it would be obvious to one skilled in the art, that voice would be impossible to function without an electronic assembly. Mault and Applicant are undeniably different using the Examiner's position along with Mault's own teachings.

As shown above, Mault's device is <u>unreliable as a sole voice operating unit as in obvious certain scenarios the electronics are not allowed which makes voice recognition, generation and recording impossible.</u> Also, it should be noted that voice generation and PDAs are not new or novel inventions. Mault teaches only voice generation in specific models, and this varies depending on what PDA is being used. This obviously appears to be why Mault stipulates precisely only: "If the PDA and module <u>combination includes</u> voice generation...voice commands may be generated to instruct...provide feedback .." (emphasis added). It is obvious that Mault

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fails on all accounts to teach or solely rely on voice for the sole function and interaction by the user of Mault's invention, as Mault is relying on only some PDAs that can be used for this function and only "if" the PDA has voice capabilities. Mault's is inconclusive regarding the function of Mault's invention. Certainly, prior to Mault, a person could use voice generation to provide voice scheduling to instruct when that person should take a medication using PDAs that were in existence prior to Mault. Applicant's invention solely relies on voice for all patient interaction as a new art, at all times, as a function of the present invention. Thus, Mault's device is not a true "self sufficient" device relating to voice, as Mault's device is not capable of providing voice at all times and obviously the PDA voice is nothing new.

Applicant's invention is solely contained within one of a plurality of individual single medical devices providing voice prompts for each device, according to each device's function. Applicant's invention is preprogrammed with voice, per the governmental guidelines, prior to receipt by the user. On the other hand, Mault only uses a known voice method as one of many ways of providing user interaction and only when the Personal Digital Assistant (PDA) has voice capabilities. Mault teaches the familiar method of voice generation, in which the user must record their own voice, using the known voice recording/recognition/generation method, obviously impractical in many medical scenarios, showing a need for improvement due to inconsistencies. Also, it should be noted; Mault's PDA/monitor module system does not require any specific method for user interaction for its function, as Mault does teach voice as being required for the function of Mault's invention as Mault states: "any suitable method for patient interaction is acceptable to provide the function of the PDA" (See Mault Col. 24, Il. 64-67). Thus, making voice a method that could be eliminated completely under Mault's own teachings. Also, Mault solely requires verbal input by the patient before Mault's device will even work to provide verbal function for Mault's invention, thus, making Mault's PDAs/module system non operational without patient assistance. It is known by one skilled in the art, that voice generation existed as a function of selected PDAs prior to Mault. Mault's device cannot provide verbal messages or even function on its own without patient assistance. See Mault Col 6, II. 64-65 "For example, a particular user may specify that they will walk or run a certain number of times and for a certain distance each week," and Col 7, IL 10-11" The user may then insert the appropriate

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module into the PDA". Applicant requires no user input, i.e. verbal or manual, to be provided by Applicant's user, in order for Applicant's medical device to function, or provide voice. Applicant's device is ready for use and fully programmed with full voice capabilities prior to receipt by the user. Mault requires the user to provide voice generation, recognition and recording in order to constitute all voice instructions and also requires the user to attach and calibrate Mault's device for operation of Mault's PDA/monitor module system. These are difficult tasks for an ill person. It is unarguable, that Applicant's invention is a true completely self-sufficient, self-operating talking medical device, requiring no patient/user voice input, or calibration, or patient assistance or participation to function on its own. Mault and Applicant are different inventions. Obviously, Mault is not a true self-sufficient, self operating, talking medical device, as it does not provide a new or novel voice and relies on assistance to function as PDA voice is not new or novel.

As another non-exhaustive example: The Examiner has taken the position in the previous OAS that Mault and Applicant are both typical computers, having the same electronic assembly. See Page 5 and 6 of September 14, 2010 OAS "..the Examiner "interprets the PDA as a self-contained electronic assembly" and "Mault's PDA is a typical computing device...". Please note the Examiner's previous OAS in Applicant's U.S. Application Serial No. 11/833,787: The Examiner inherently allows and acknowledges the utilization of a functional program in comparison to the cited reference (See Page 10 of May 24, 2011 OAS citing another inventor's teaching "...all operations of the system is under the functional program...") With this, it is evident that the Examiner has inherently taken the position that a functional program is known and that the functional program exists in other inventions. However, when discussing Mault's typical computer, the Examiner fails to mention "functional program". Despite Applicant referencing the differences between Applicant's functional program and Mault's typical computer, in its previous remarks, the Examiner failed to address these arguments, which evidences that the Examiner obviously concedes that Mault's typical computer does not have Applicant's functional program.

It is Applicant's position that Mault does not teach a device that has Applicant's functional program. Applicant teaches a complex electronic assembly that is not typical (i.e.

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functional program). Inherently, the Examiner takes the position in previously cited OAS that the functional program is an essential in certain electronic assemblies (i.e. Kaufman). However, the Examiner is silent as to Applicant's functional program regarding Mault, as Mault does not teach Applicant's functional program. Applicant's functional program is totally related to the voice function of Applicant's device and shows significant difference between the electronic assembly of Mault and the electronic assembly of Applicant.

In order to keep the continuity of the function of the present invention, the Applicant again refers to the inherent, obviousness and present facts regarding these differences presented by the Examiner. It is commonly known by one skilled in the art that a functional program is defined as a component of computer science in only certain electronic assemblies, non-related to a typical computer, such as Mault. However, the fact that both Mault and Applicant's electronic components are similar to a typical computer does not means that the electronic assemblies are the same. It is obvious, that Mault does not contain a functional program as Applicant's electronic assembly. With this evidence, the additional functional program of Applicant's device differentiates between Applicant and Mault based on the voice capabilities of Applicant's talking medical device, making Mault's invention distinctively different from Applicant's invention. Being that Mault and Applicant are distinctively different it should be noted in relationship to verbal prompting, Applicant's device in comparison and different to Mault's device, requires no patient participation (i.e. verbal or manual) for usage. In view of the significant differences, the scope of the aforementioned electronic assemblies and functional advantages between the two inventions, the following arguments should persuade the Examiner to see the distinctive differences between the two inventions and the obvious functional usage and uniqueness regarding Applicant's particular electronic assembly which incorporates Applicant' novel functional program different than Mault.

Further Applicant teaches and claims that Applicant's invention employs an intricate, complex functional program, which is unlike a typical computer, whereas Mault does not. This is obviously why Mault requires the user to provide voice and manual input for Mault's device to work and function. Applicant's functional program is specialized for each medical apparatus for which it is associated with and housed therein. Please note, Applicant's "functional program" is

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specifically programmed for involvement in the computation and evaluation of mathematical and logical functions for controlling Applicant's electronic assembly. See Page 11, Il. 3-5 "through the function of the present invention as specified herein, capable of performing mathematical and logical calculations" and decision logics which together constitute the "functional program". The functional program deciphers the particular usage of the associated medical apparatus in order to produce appropriate exact verbal prompts, phrases, measurements, etc. specifically related to the use of the associated medical apparatus. When viewed against Mault's device, Applicant's electronic assembly, containing this specialized functional program, is "vastly" different than Mault's and operates according to the defined functions of each specific medical apparatus for which it is contained therein. The functional program of the Applicant determines each verbal prompt, phrase, result and/or measurements, according to the 1000's of verbal prompts and these verbal instructions are in compliance with the governmental medical guidelines. If Mault is capable of employing voice, then Mault teaches; the user to use voice recording and voice generation in order for Mault's device to provide voice instructions. Mault Col 5, Il. 4-18. Applicant requires no user participation for voice to be automatically supplied by Applicant's device.

When comparing Mault's typical computer to the Applicant, it becomes obvious that the Applicant's functional program automatically uses internal logic, which is transferred directly from the present invention to each medical device, in order to specifically decipher and select the next customized verbal prompt, phrase and/or voice measurement. This process is done in relationship to what the patient/user has previously performed regarding the patient's use and measurement provided by Applicant's invention, in order to increase patient recovery. Thus, this process requires no patient voice input or participation from the user, in comparison to what Mault teaches, regarding voice generation, recognition and recording making both inventions different from each other. From these determinations, the Applicant's functional program precisely provides a correct annotation of the needed verbal measurements relating to the patient's needs. This is done by providing verbal encouragements and verbal disapproval messages based on the therapeutic performance of the each specific medical device employed by the user. All voice of the Applicant's invention is preprogrammed in advance, prior to patient

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receiving each device and is contained within the Applicant's functional program. Mault's PDA/module system is not. Thus, the functional program of the Applicant shows a distinctive difference between Mault's user required programming and Applicant's preprogrammed voice.

No numerical verbal/voice measurements from using any of the Mault physiological monitors are provided as taught by Mault. Rather, Mault relies on a display to provide the non-verbal results, instructions, etc. to the user. (Mault Col 7, Il. 62-63 "The display 22 of the PDA is used to communicate information from the module 12 to the user."

Contrary to Mault, Applicant's invention uses specific and detailed preprogrammed verbal prompting and encouragement messages that do not require voice participation of the user and also automatically provide verbal measurements simultaneously with display, if needed, on its own. Such numeric measurements are verbally supplied by Applicant's device itself. Applicant's unique invention automatically verbally communicates to the user measurements during use and after a scheduled therapeutic session, by providing verbal instructions. It is obvious that Mault is silent concerning providing "any" voice measurement. In fact, "voice measurement" is not in Mault's patent. It is obviously known that measurements are a requirement for obtaining data for medical diagnosis of patient health status and a necessity for use in all true medical devices. No verbal input is required by Applicant's user to receive verbal prompting or verbal measurements from Applicant's device, in comparison to Mault. Thus, Applicant's device is obviously a different invention than Mault's device, as Mault always requires user/patient verbal input in order to provide voice instructions for Mault's device, and only when available according to the PDA being used. Applicant's invention requires no user input to perform "any" of the functions of the present invention and requires no assistance or patient participation, making the respective inventions distinctively different. With the Examiner now taking the position in the most current OAS that; the monitor module and the PDA are separate stand alone devices, (Pg. 4 of 6-9-2011 OAS - "further discussions of the PDAs capabilities are equivalent to a stand-alone modules capabilities"), it is obviously undeniable that Mault and Applicant are different inventions. This is especially evident if the module and PDA are both stand alone devices (using the examiner's position), there is no need for either component to rely on each other, as they are both are separately independent individual devices.

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The Examiner has taken the position in previous Office Action summaries that; "Mault's PDA/module system is a common housed device." Now inherently, to the contrary, the Examiner has proclaimed the PDA and module work separately with the same electronic assembly, thus, being distributed parts as stand-alone devices (Pg. 4 of 6-9-2011 OAS – "further discussions of the PDAs capabilities are equivalent to a stand-alone modules capabilities"). With this understanding it is obvious that Mault teaches the same position as the Examiner regarding distributed parts and lack of common housing (See Mault Col. 4, II. 30-32 "The PDA need not be a unitary device, but instead the components could be distributed."). With this evidence, it is obvious that Application is distinctively different as Applicant's invention is solely contained within the housing of each of the "single" talking medical devices that Applicant teaches and the components are non-distributed. To the contrary of Mault, Applicant's invention is a self-contained, single housed device at all times, without "any" distributed components. Obviously this shows a distinct difference between Mault's and Applicant's inventions.

The Examiner also interprets Mault to be similar to Applicant's invention, because they both provide initial prompts to inform the user to begin usage. (See Office Action Summary "OAS" Page 5 and Page 6"...the patient is prompted periodically by the PDA to make use of the various physiological monitor modules as part of an overall health management..." and "although Mault does not distinctly disclosed that the PDA's prompts contain verbal messages, it does teach that the PDA and various monitor modules have voice generation capabilities for generating voice commands to instruct and provide audio feedback to the user... It is the Examiner's position that this is sufficient to reject verbal messages." With the lack of the aforementioned electronic assembly of the previously mentioned calorimeter module, it is evident that the periodic prompts can only be performed in certain scenarios and lack thereof of an electronic assembly, as taught by Mault and previously identified as evidence, that Mault cannot work for verbal functions as a self sufficient, verbally prompting medical device. With this said, the Applicant must rely on common sense to prevail. With this understanding, Mault obviously is not a true self-sufficient, self-operating talking medical device, as Mault's patient must first provide the verbal setup in order for Mault's voice to work. Mault Col 5, II. 9-11 "If voice recording or recognition is available, this capability may be used.". Accordingly, the

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Examiner's interpretation is inconsequential regarding any similarity to Applicant, as Mault's device cannot work by itself. If the patient is not present to participate, Mault's device cannot function.

Applicant's invention is preprogrammed and automatically provides verbal instructions without any verbal commands from the user to set up any subsequent reminders or timing counter as Mault does; "always requires user input (i.e. verbal or manual) to function". It is obvious to one skilled in the art, that Mault and Applicant are distinctively different, as obviously the timing counter of Mault is not the same as Applicant. If the patient is not present, Mault's device cannot work.

Mault continuously teaches the PDA/module system for overall healthcare management and fitness purposes, however, Mault also teaches other unrelated uses (Col 24, Il. 39-40 "Designed to mount on the handlebars of a bicycle with a PDA"), and is using the system for non-medical purposes only. Obviously, a bicycle handle is not a medical device. Mault does not teach the use of medical therapeutic guidelines, which are always necessary for patient recuperation when using the appropriate medical device, after surgery or recovering from a medical condition. Mault is teaching a way to benefit a user who is in good health for everyday healthcare purposes. Mault Col 6., Il. 30-32 "Preferably, the various embodiments of the present invention are used as part of a weight or health management system,..". Mault does not teach therapeutic usage for any of Mault's devices obviously due to this reason. To the contrary, Applicant's device is meant for the patient/users who are "not in good health" and do not pertain to fitness as Mault teaches, and thus requires therapeutic exercises (through therapeutic guidelines) to be performed, in order for patient recuperation and to improve user/patient health over time in a true medical scenario. See Applicant, page 1, Il. 31-32 "...in order to improve the patient's health or medical condition,"; page 9, line 21 "...given to the patient to help in their recovery..."; and page 10, line 13 "...will also help decrease the recuperation time of the patient...". Mault is silent concerning any patient health conditions. Rather, Mault emphasize use of Mault's device based on healthcare and fitness and Mault never specifies the need for therapeutic guidelines. Mault Col 6, Il. 44-45 "This is a very important factor in dietary management." and Mault Col 6., Il. 47-49 "The data from the measurement is then automatically

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entered into the health management program." Using the Examiner's previous position regarding therapeutic guidelines, inherently relied on in previous OAS (September 14, 2010), this difference regarding patient usage is significant and should persuade the Examiner that Applicant's invention is not the same as Mault.

Another important feature for Applicant's invention is the sequence of verbal prompting is different based on which specific medical apparatus is being used with and the necessary therapeutic session performance required. All of these verbal prompting messages and therapeutic guidelines are preprogrammed and specifically automated within each device being used by the Applicant's user. Applicant's and Mault's invention are significantly different.

Mault never teaches any therapy or therapeutic guidelines relating to Mault's invention. With the understanding that the Mault user must provide verbal setup input to the Mault device for the device to provide any voice messages, this would require the Mault user to have medical knowledge as to what message to provide in relationship to medical guidelines. It is obvious that any normal patient/user would not possess such knowledge. Thus, the user would be required to select the appropriate scheduling message for therapeutic guidelines (i.e. inhalation procedures, exhalation procedures, when to take pulse rate or blood pressure, etc.). Obviously, no healthcare related patient would be capable of doing this. Mault is silent in relationship to any disclosure or teaching of providing any of these claimed verbal therapeutic guideline messages which relate to medical.

It is known that the various embodiments of individual physiological monitors of Mault's invention allow it to perform Mault's claimed functions as different combinations of modules and PDAs. The function of Mault's components are not constantly the same. Mault never specifically described any one PDA for the function of Mault's invention. Applicant is just the opposite of Mault. Applicant's invention is within each individual medical device and the electronic assembly always remains the same (within the medical device housing). This is further evidenced by the fact that the Applicant's electronic assembly does not have its own housing, as Applicant's invention must be contained within the traditional housing of the medical devices themselves. Thus, to the contrary of Mault, the electronic assembly of Applicant's invention is contained, at all times, within the housing of the specific medical device that it is associated

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with, making Applicant and Mault different inventions. Furthermore, the same electronic assembly of Applicant is associated with each specific existing medical device to provide function for each specific medical device for which the electronic assembly is contained within. Mault is not. As such, the electronic assembly of Applicant's invention is specifically preprogrammed to each specific medical device that it is associated with. Mault's single PDA acts as a separate computing device having many configurations, with the single PDA being one of many PDAs that can be used according to the user's discretion. Mault is difficult for the user to configure or operate in order to provide any specific function. Mault's PDA/module system is not preprogrammed for only one specific medical device, as it up to the patient to program Mault's device as the patient chooses.

Applicant's therapeutic schedule is preprogrammed based on established therapeutic guidelines for the specific medical device that Applicant's invention is contained within without changing the electronic assembly (i.e. Mault's variety of PDA choices as no one PDA is specified for usage by Mault in all scenarios). (See Applicant's Specification Page 22, IL 3-6 "The above organizations and associations allow the present invention to be programmed conforming to the guidelines established for medical apparatuses and devices associated with these therapeutic guidelines established by the government."). Obviously, the previous OAS dated September 14, 2010, the Examiner has taken the position that therapeutic guidelines are inherently known and commonly used for medical devices. Mault fails to teach Applicant's invention of having preprogrammed verbal messages in advance prior to the patient receiving the medical apparatus and also fails to have any preprogrammed schedule that pertain to any established medical therapeutic guidelines. Mault's PDA/module system is constantly changing in order to operate properly. Mault Col.5, Il. 1-3 "When the monitor module is not in use, the PDA may be removed and used for alternative purposes, possibly with other modules." Applicant's invention does not require any manual or verbal assistance from user, which Mault obviously does. Col. 10, Il. 53-56 "In order to use the device, the user first inserts the attachment flange 62 into the accessory slot to couple the spirometer module 60 with the PDA 66." In fact, the Applicant's invention is preprogrammed prior to the user receiving each medical device. Applicant's invention automatically determines when the user has performed the necessary

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therapeutic steps and provides an appropriate verbal message, instruction or measurement to the user without any subsequent user input or human assistance. The Applicant's electronic assembly (upon the completion of the therapeutic sessions), needs "no" manual calibration, participation or steps by the user (verbal or otherwise). Applicant's invention automatically performs voice interaction with the patient totally on its own. Mault does not. Mault's invention cannot provide a medical instruction at any time unless a user is first available to make a voice recording. Mault's PDA/module system is useless for providing voice, without the user first recording his or her voice. Obviously, Mault's PDA/module system will not function at all without a user being present. Applicant's unique medical voice function is contained within the actual medical device and the patient utilizes the Applicant's device the same as a normal medical device would be used as they are in the same housing. Mault is not. Applicant's invention automatically provides all of its voice functions on its own from within the medical device and without any patient voice commands being required. See Applicant's Specification Pg. 6, IL 17-20"...to not allow the patient to have any control over the medical apparatus that is being used in relationship to the function of the present invention rather only allow the patient to follow the directions provided as herein mentioned by the present invention." Obviously, Mault and Applicant are distinctively different.

As detailed in Applicant's specification, Applicant's functional program is a programming paradigm that uses computations and mathematical functions specific to the medical device that the functional program is contained within. See Applicant Page 11, II. 4-5 ("The present invention is "capable of performing mathematical and logical calculations and decision logics which together constitute the 'functional program'"). Mault is different from Applicant as Mault does not teach the ability to use mathematical computations to derive "any" threshold level based on specific therapeutic guidelines for the medical device. Applicant's invention is a preprogrammed device that is ready for use prior to receipt patient/user, without any patient input. Applicant's device requires no user input to properly function. Mault's PDA/modules are removed and passed between other modules (i.e. patients). Mault Col.5, II. 1-3 "When the monitor module is not in use, the PDA may be removed and used for alternative purposes, possibly with other modules." Obviously, Mault allows usage of one PDA by more

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than one user at one time with separate modules. Applicant does not. In comparison, obviously the two inventions are distinctively different, as Applicant's device requires no verbal participation, voice input or calibration from the user at any time in order to perform the function of Applicant's invention. Mault always requires user participation, verbal and manual, to operate.

The Examiner has interpreted inherently through the previous OAS dated May 24, 2011 (Serial No. 11/833,787) that it is known that medical devices follow therapeutic guidelines. Obviously, the Examiner's position is that therapeutic guidelines are required for patient safety and guidance. For purposes of distinguishing Applicant's invention from Mault's invention, Applicant will follow the Examiner's interpretations for this instant response, signifying that Mault fails to teach the Examiner's previously stated position. It is commonly known that the medical guidelines for medical devices are essential for proper utilization. Medical guidelines are required by the United States of America to govern the specific usage of all medical devices (i.e. American Medical Association "AMA", Food & Drug Administration "FDA", American Association for Respiratory Care "AARC", etc.). These medical guidelines are provided for safety and proper usage of medical devices in order to help patients reach their goals, as needed for proper recovery to ensure that the patient's therapeutic goals are performed with patient safety in mind. Thus, it is known by one skilled in the art that following the therapeutic guidelines therefore set by the governmental agencies of the U.S. are essential part of patient recuperation and a requirement of all medical devices. Mault is silent concerning "any" medical or therapeutic guidelines for any of Mault's devices. Mault is distinctively different than Applicant.

As the Examiner has interpreted Mault's medical devices, which is *inherently* the Examiner's position, as being used for therapeutic purposes for medical device usage, than it follows that the devices taught by Mault would have to be used in accordance with the established medical guidelines as well. It is known that medical guidelines are established by regulatory agencies, such as the FDA, AMA, AARC, etc. However, Mault fails to provide any disclosure of Mault's invention using therapeutic guideline or having a functional program being in accordance with any established governmental guidelines for any medical procedures taught by Mault. Rather, Mault allows the user to verbally input voice recognition, recording,

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generation for establishing scheduling according to the patient's discretion as opposed to any safety guidelines. Mault is not a governmental regulated medical device, as Applicant's invention is, as the Mault user obviously chooses to operate Mault's monitor modules however they see fit. Using Mault's invention, one could not expect the patient to provide the correct and proper verbal prompts or commands relating to any specific operations needed under the required therapeutic guidelines for any medical device (such as when a test should occur in order to ensure patient recovery). Though under healthcare or physical fitness as Mault teaches, this is certain understandable as such knowledge is not required of the user. As already noted above, in addition to the Mault user having to verbally input the voice and testing schedules on their own, Mault's device must perform additional verbal and manual user input. Given the amount of input and assistance (verbally and manually) required by Mault's user, it is not surprising that Mault's devices are used for healthcare and fitness purposes. Col. 2, Il. 4-5 "This information is extremely helpful in health and fitness management...". Common users of Applicant's invention are patients who are not in "good health" and are using the medical device for recuperation. (See Applicant Page 2, Il. 1-3 "For instance, during recuperation after surgery a patient is required to repeatedly use ventilators with special gases to help moisturize the lungs, that during an operation usually collapse."). Obviously, Mault is not a true talking medical device and it has many limitations. Applicant's device is complex and Applicant's device provides the proper verbal prompts in any scenario, where Mault's PDA/module system does not. Mault will not work without a user being present.

It is commonly known that all medical devices require measurement data to achieve any therapeutic or diagnostic conclusion for patient health condition in order to decipher and prescribe medical attention. Verbal measurements are essentially important for those who are visually impaired. However, Mault is silent concerning any "verbal" or numerical measurements for Mault's invention. Applicant's device always provides verbal numerical measurements at all times as needed. See Applicant's Specification Pg. 4, Il. 15-17 "...the present invention gives an added benefit through providing audible, verbal word, words, or phrases making the present invention not only valuable to the sighted, but a important benefit for the blind,..." This obviously shows that Mault is distinctively different from Applicant.

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Furthermore, for patients who have had throat surgery or other procedures requiring the patient to need an artificial breathing device, the patient's throat is affected preventing the patient from talking during the hospital stay. With this in mind, if the patient cannot talk, then Mault's device cannot provide verbal instructions or prompts, as Mault's invention requires user input (i.e. verbal and manual) to be given to operate Mault's PDA/monitor module, in order for any voice to be provided using voice generation.

Applicant's invention is preprogrammed to provide the patient user with verbal commands, instructions, guidance and verbal measurements, throughout the use of the medical device, as well automatically providing verbal prompts, instructions, therapeutic schedule requirements, without any patient verbal input to receive Applicant's verbal functions. Therefore, Applicant's device can still be used by a patient who is unable to speak. Contrary to Mault, none of these benefits from Applicant's claimed invention can be provided by Mault. Applicant's functional program, unlike Mault, is fully preprogrammed within the medical device for which it is contained in order to assist the patient, and does not impose tasks (i.e. verbal input by user) on the patient (verbally or manually). The functional program provided by the Applicant shows the fact as to why Applicant's user is not required to be involved with the programming of Applicant's non-programmable medical devices in comparison to Mault. See Applicant Page 8, Il 28-29 "...combined with the above said apparatuses at whatever degree of complexity is required to supply the necessary function." Applicant's invention is fully preprogrammed prior to receipt by the user. Thus, the limitations of the patient's actual knowledge of the medical device or medical guidelines do not come into play or play a role in the preprogramming of Applicant's invention as Applicant's invention is preset to the specific therapeutic guidelines required with the governmental medical guidelines, prior to the patient receiving the device and unlike Mault, requires no patient input. Rather, Applicant's invention is user friendly and the Applicant's device can function without the patient having any previous knowledge of the medical device or the therapeutic guidelines associated therewith. Obviously, Applicant's invention and Mault's invention are distinctively different.

It is obvious to one skilled in the art that Mault is not a true self-sufficient talking medical device, as it does not automatically work by itself and is not self-operating as Mault requires the

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user to first enter verbally input before it will send a verbal message. In use, In addition to not being a self-operating unitary device. Mault also fails to provide for a single housed assembly as Mault's PDA/monitor module is made up of many separate distributed parts, unlike Applicant's one housed device. See Mault Col. 4, II.30-32 "The PDA need not be a unitary device, but instead the components could be distributed." As claimed by Applicant, Applicant's device is completely self-sufficient and self-operating and does not have distributed parts. With these readily apparent differences between Mault and the Applicant, it is obvious that Mault does not meet the definition for a true talking medical apparatus, as the scope of Mault's present invention does not constitute a self operating talking apparatus at all times, if at all. This makes Mault's voice limited and undependable according to whether Mault's PDA has voice capabilities when a patient needs to use Mault's device, as in some instances voice is unavailable. Mault obviously teaches the PDA/module system that is not dependent on any voice to provide function, as if the patient is not providing voice from Mault's PDA/monitor module the use of voice in Mault's invention is impossible. However, Mault's PDA/monitor module still will function without voice through other means and Mault makes it perfectly clear that voice is not required for the function of Mault's invention.

Synthesized Voice

Regarding synthesized pertaining to voice of Mault's other patent the Examiner requested the Applicant to read. After reading, it is obvious that the fact that Mault intentionally choose voice generation, due to the fact that it allows the patient to program it. Mault teaches that his PDA/module system excludes non-programmable devices. Mault Col 4, Il. 39-40: Mault teaches "dedicated and non-programmable devices" are excluded for the function of Mault's invention. Voice generation, is known to be programmable, and voice recognition and recording can be problematic to achieve, especially by a person of good health. In any event, Mault's voice does not work without a user being present, thus, Mault's device is undependable. If Mault's patient is not present, Mault's device cannot work.

In today's world, letters, messages and cards can be sent electronically via email. However, it is still the practice that the U.S. postal service remains the standard for sending letters, messages and cards even though this method could be replaced. With this understanding,

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the traditional ways continue to be the accepted way, as it is with medical devices as well. In the

same sense this is true regarding the Applicant's invention, though there is technology having the

ability to replace standard medical devices, such as Mault. Thus, Applicant's invention

intentionally and specifically improves, enhances and uses traditional standard medical

equipment that is commonly known by the medical industry. Mault replaces medical devices,

Applicant enhances and improves medical devices. Mault and Applicant are distinctively

different inventions.

For all of the above reasons, Applicant respectfully hopes the Examiner is persuaded to

withdraw the rejection based on Mault.

In view of the above, Applicant respectfully submits that the claims are all in condition

for allowance. Applicant respectfully requests that the Examiner withdraw the objections and

rejection. Accordingly, favorable action, allowing all of Applicant's claims, is respectfully

requested. Applicant has completely responded to the June 9, 2011 Office Action.

If there are any additional charges, including extension of time, please bill our Deposit

Account No. 503180.

Respectfully submitted,

/Daniel S. Polley/

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